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moxidectin for use as in paragraph (d)(2) of this section.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Topically apply 4.5 mg/lb body weight (10 mg/kg) imidacloprid and 1.1 mg/lb (2.5 mg/kg) moxidectin, once a month.

(ii) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*; and the treatment and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), and whipworms (*Trichuris vulpis*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

(2) *Cats*—(i) *Amount*. Topically apply 4.5 mg/lb body weight (10 mg/kg) imidacloprid and 0.45 mg/lb (1.0 mg/kg) moxidectin, once a month.

(ii) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis*; for the treatment and control of ear mite (*Otodectes cynotis*) infestations, intestinal roundworms (*Toxocara cati*), and hookworms (*Ancylostoma tubaeforme*); kills adult fleas and treats flea infestations (*Ctenocephalides felis*).

[72 FR 10597, Mar. 9, 2007]

§ 524.1193 Ivermectin topical solution.

(a) *Specifications*. Each milliliter (mL) of solution contains 5 milligrams of ivermectin.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) Nos. 050604, 055529, 058829 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(iii), and (e)(3) of this section.

(2) Nos. 054925, 059130, 061623, and 066916 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii), and (e)(3) of this section.

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Special considerations*. See § 500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount*. One mL per 22 pounds (0.5 milligram per kilogram) of body weight

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applied topically to the back of the animal.

(2) *Indications for use*—(i) It is used for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. surnabada*, *Oesophagostomum radiatum*; (adults) *Strongyloides papillosus*, *Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis*, *H. lineatum*; mites *Sarcoptes scabiei* var. *bovis*; lice *Linognathus vituli*, *Haematopinus eurysternus*, *Damalinia bovis*, *Solenopotes capillatus*; and horn flies *Haematobia irritans*.

(ii) It controls infections and prevents reinfection with *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *C. punctata*, and *C. oncophora* for 14 days after treatment.

(iii) It controls infections and prevents reinfection with *O. radiatum* and *D. viviparus* for 28 days after treatment, *C. punctata* and *T. axei* for 21 days after treatment, *O. ostertagi*, *H. placei*, *C. oncophora*, and *C. surnabada* for 14 days after treatment, and *D. bovis* for 56 days after treatment.

(3) *Limitations*. Do not treat cattle within 48 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal.

[55 FR 50551, Dec. 7, 1990, as amended at 62 FR 38908, July 21, 1997; 62 FR 63271, Nov. 28, 1997; 63 FR 44385, Aug. 19, 1998; 66 FR 13236, Mar. 5, 2001; 66 FR 63165, Dec. 5, 2001; 68 FR 3817, Jan. 27, 2003; 68 FR 4713, Jan. 30, 2003; 69 FR 501, Jan. 6, 2004; 69 FR 62181, Oct. 25, 2004; 71 FR 13542, Mar. 16, 2006; 72 FR 6464, Feb. 12, 2007; 74 FR 36112, July 22, 2009; 75 FR 26648, May 12, 2010]

§ 524.1195 Ivermectin otic suspension.

(a) *Specifications*. Each tube contains 0.5 milliliter (mL) of a 0.01 percent suspension of ivermectin.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer the contents of one 0.5-mL